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18M1/0424

EXAMINER	
LEE, D	
ART UNIT	PAPER NUMBER
	1815

DATE MAILED: 04/24/97

Below is a communication from the EXAMINER in charge of this application  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### ADVISORY ACTION

##### ☒ THE PERIOD FOR RESPONSE:

- a) ☒ is extended to run 4 months or continues to run \_\_\_\_\_ from the date of the final rejection
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).
- ☐ Applicant's response to the final rejection, filed \_\_\_\_\_ has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
  - ☐ They raise new issues that would require further consideration and/or search. (See Note).
  - ☐ They raise the issue of new matter. (See Note).
  - ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☒ will be entered ☐ will not be entered and the status of the claims will be as follows:

Claims allowed: \_\_\_\_\_  
Claims objected to: \_\_\_\_\_  
Claims rejected: 7, 8, 16

However:

- ☒ Applicant's response has overcome the following rejection(s): 102/103(a) Lee et al (1985, 1986)

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because (see attachment)
5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.
- ☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.
- ☐ Other

### DETAILED ACTION

1. Receipt is acknowledged of applicants' amendment after final in Paper No. 10, filed 3/18/97, wherein claims 7-8, 16 are amended and no new claims are presented. Accordingly, claims 7-8, 16 are under consideration in the present application.
2. Rejection of claims 7-8 and 16 under 35 U.S.C. 102(b) as anticipated or 35 U.S.C. 103 as being obvious over either Lee et al. (Applicant's AA1) or Lee et al. (Applicant's AW) is **withdrawn**.
3. Rejection of claims 7-8 and claim 16 under 35 U.S.C. § 103 as being unpatentable over Lee et al. (AA1) or Lee et al. (AW) in view of Luckow et al. (AO) or Matsuura et al. (AP) is **maintained** for the reasons of record.

Applicant's arguments filed 3/18/97 (paper No. 10) have been considered are not deemed persuasive. Applicant argues that the novel plasmid pAcDSM, is engineered to receive the foreign gene precisely at the translation initiation codon of the polyhedron gene, without missing any nucleotide present in the native 5' nontranslated leader sequence is noted, but these limitations are not in the claims. The claims are drawn to a purified herpes simplex virus gG1 and/or gG-2 antigens and not toward the baculoviral expression system. Applicant's claims constitute a product-by-process type claims and the burden is upon applicant to demonstrate the distinction between the material, structural and functional characteristics of the claimed composition and the compositions of the prior

art. Applicant argues that the protein made by the expression system of Sanchez-Martinez and Pellett, may differ from the art because of the differences of the transfer vector.

Lee et al (1985) and Lee et al (1986) teach purified natural HSV glycoprotein gG-1 and gG-2.

*Luckow et al. discloses the development of baculovirus expressions systems and the advantages of using such systems for "the very abundant expression of recombinant proteins, which are in many cases, antigenically, immunologically, and functionally similar to their authentic counterparts" (see page 47, first column, first full paragraph). Neither Luckow et al. or Matsuura et al. teach the expression of gG-1 or gG-2 peptides in baculovirus expression systems. However, the level of ordinary skill in the genetic engineering art is exceptionally high and, absent convincing objective evidence to the contrary, it would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to express the gG-2 protein of Lee et al. (AA1) or the gG-1 protein of Lee et al. (AW) in the baculovirus expression system of Luckow et al. or Matsuura et al. for the expected benefit of obtaining high levels of expression of gG-1 and gG-2 proteins suitable for use as diagnostic or immunological reagents. One of ordinary skill in the art would have been motivated to express the proteins in a baculovirus system since Luckow et al. and Matsuura et al. disclose the numerous advantages of baculovirus expressions systems and one of ordinary skill would have had a reasonable expectation of success since Luckow et al. and Matsuura et al. both establish that the baculovirus system produces significant amounts of peptides and that such peptides "are in many cases, antigenically, immunologically, and functionally similar to their authentic counterparts." More ever, the selection of a particular transfer vector is deemed to be a result-effective parameter routinely optimized by the artisan of ordinary skill as taught by Matsuura and Luckow.*

*Luckow et al. also discloses many of the vectors suitable for baculovirus expression systems and the importance of particular leader sequences upstream from the polyhedron gene ATG and their impact on protein production (see page 51, first column, last paragraph). Similarly, Matsuura et al. also discloses the uses and advantages of the*

*baculovirus expression system and teaches "that the immediate 5' upstream sequences are important for high level expression" (see page 1234, Figure 1 and see page 1247, second full paragraph).*

Thus, the transfer vector disclosed in the specification is deemed obvious under 35 U.S.C. §103.

In conclusion, applicants (product-by-process) recombinant proteins is made obvious by the Lee et al (1985), Lee et al (1986), Matsuura and Luckow. Applicant has failed to provide convincing evidence and arguments to support a patentable distinction between the proteins of the prior art and those claimed by applicants.

No claims are allowed.

Papers relating to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 located in Crystal Mall 1. The Fax number for Art Unit 1813 is (703) 305-7939. All Group 1800 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Danny Lee whose telephone number is (703) 305-7245. The Examiner can normally be reached on Monday-Tuesday from 8:00 AM-6:30 PM, (EST) and Thursday-Friday from 8:00 AM-6:30 PM (EST).

Serial Number: 08/480,850

Art Unit: 1815

Examiner: Danny Lee

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Page 5

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Marian Knode, can be reached at (703) 308-4311.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Danny Lee

April 21, 1997



**MARIAN C. KNODE  
SUPERVISORY PATENT EXAMINER  
GROUP 1800**